REMARKS

The outstanding Office Action requires that Applicants elect one of the following five (5) allegedly distinct inventions:

I. Claims 1-11, drawn to a process of treating a disease with the administration of a mammalian intermediary metabolite, classified in Class 435, subclass 262;

II. Claims 12-24, drawn to a process of treating a disease with the administration of a reagent, classified in Class 435, subclass 262;

III. Claims 25-36, drawn to an ex-vivo process of treating a disease with the administration of a mammalian intermediary metabolite, classified in Class 435, subclass 267;

IV. Claims 37-49, drawn to an ex-vivo process of treating a disease with the administration of a reagent, classified in Class 435, subclass 267;

V. Claims 50-62, drawn to a process of treating a disease with the administration of a mammalian intermediary metabolite, classified in Class 435, subclass 262.

Applicants respectfully request reconsideration of the Restriction Requirement in view of the following remarks concerning the elections made herein.

First, restriction between inventions is only proper when a search burden exists for the Examiner to search all of the inventions claimed. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions (see MPEP §803.01). In the instant case, all five Groups are drawn to methods of treating disease. Further, Groups I, III, and V are all drawn to administering a metabolite and Groups II and IV are both drawn to administering a reagents which increase metabolite levels. Therefore all five Groups are related in their use of metabolites for treating disease, either directly or indirectly. In addition, all five Groups are in classified in 435, with Groups I, II, and V sharing the same class and subclass

(435/262) and Groups III and IV sharing the same class and subclass (435/267). Therefore it is evident from overlapping method steps, overlapping class and subclass, and overlapping preambles, that a search of the subject matter of Groups I, II, III, IV, and V does not constitute a serious search burden for the Examiner.

Secondly, the Office Action did not elucidate reasons and examples as required by MPEP 803 to support restriction between the three diseases (cancer, infection, and immune dysfunction) as distinct and independent. It is also unclear from the Office Action whether this second requirement was a restriction between inventions or a species election. Applicants note that the subject matter of the Groups focuses on administering an metabolite and as such search of the use of a metabolite will encompass several diseases including but not limited to cancer, infection, and immune dysfunction. For instance, the specification teaches that the immune system monitors both infection and metabolic processes (pp. 8). Thus the immune system, and hence infection by both bacteria and viruses, is linked to immune dysfunction. Also, the immune system is intimately involved in the regulation of tumor cells. Further the specification teaches that HCV causes both immunosuppressive and immunoreactive responses in an infected subject demonstrating the relationship between immune dysfunction and infection (pp. 9).

Thirdly, the Office Action did not elucidate reasons and examples as required by MPEP 803 to support restriction between two infectious agents (bacteria and viruses) as distinct and independent. It is also unclear from the Office Action whether this third requirement was a restriction between inventions or a species election. Additionally, it is improper to restrict between bacterial and viral infection as the preamble of the method claims centers on treatment of a disease using a metabolite or a reagent which increases metabolite levels. Also search of the use of a metabolite or reagent which increased metabolite levels would encompass both bacterial and viral infections.

Further, the Office Action did not elucidate reasons and examples as required by MPEP 803 to support restriction between three viruses: HBV, HCV, and HIV. All three viruses infect the same host (humans) via a similar transmission method and often co-infect the same individual. Thus the three viruses share a common structure and function in accordance to *In re*

Harnish 631 F.2d 716, 206 USPQ 300 (CCPA 1980) and it is inappropriate to restrict between the three viruses.

In view of the above remarks, it is respectfully requested that the Restriction Requirement be withdrawn and that all claims be allowed to be prosecuted in the same patent application. In the event that the requirement is made final and in order to comply with 37 C.F.R. § 1.143, Applicants reaffirm the election with **traverse** of claims 12-24 (Group II), holding claims 1-11 and 25-62 in abeyance under the provisions of 37 C.F.R. § 1.142(b) until final disposition of the elected claims.

CONCLUSION

Applicants maintain that the restriction requirement is improper and that all pending claims, *i.e.*, claims 1-62, should be examined for patentability. If the Examiner believes that the prosecution might be advanced by discussing the application with Applicants' representatives, in person or over the telephone, we would welcome the opportunity to do so.

Respectfully submitted,

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